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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/584,242 | 06/23/2006 | Yusuke Murakawa | 084437-0169 | 1685 |

22428 7590 04/09/2008
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| EXAMINER |
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DICKINSON, PAUL W

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| ART UNIT | PAPER NUMBER |
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1618

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| MAIL DATE | DELIVERY MODE |
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04/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/584,242 | MURAKAWA ET AL. | |
| | Examiner | Art Unit | |
| | PAUL DICKINSON | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/2006 and 9/22/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-9) in the reply filed on 2/20/2008 is acknowledged.

Applicant's election without traverse of Compound X in the same reply is also acknowledged. The Restriction Requirement mailed 1/23/2008 did not, however, require a species election. The Examiner is therefore not restricting the examination to the elected species.

Claims 1-9 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "at least about 35%" in Claim 2 is vague and indefinite. It is unclear what ranges are encompassed by this phrase. "At least" is a minimum that encompasses all possible values above 35%, whereas "about 35%" encompasses possible values both above and below 35%. The phrase "about 20% by weight or more" in Claim 7 is vague and indefinite for similar reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 0243704 (hereafter WO '704; US 20040076675 ('675) is an English equivalent and will be referenced hereafter). WO '704 discloses a pharmaceutical granulated product comprising a slightly water-soluble medicament (a pharmaceutical compound with poor wettability) and a surfactant (see '675: abstract; Examples; Claim 1). The disclosed granulated product provides improved solubility and oral absorbability, which the Examiner is interpreting as one embodiment of improved granulatibility as recited in Instant Claim 1 (see '675: ¶ 1). WO '704 discloses an example wherein the weight ratio of Compound (Ia) (a pharmaceutical compound with poor wettability) and sodium lauryl sulfate (a surfactant) is 1:2 (see '675: Example 1). WO '704 discloses 0.3 g pharmaceutical compound per gram of granulated product, which corresponds to 30% pharmaceutical compound by weight (see '675: ¶ 58; calculated from $(0.3/1) \times 100\%$). WO '704 further discloses molding the granulated product into tablets and capsules, which the Examiner is interpreting as one embodiment of a molded product as recited in Instant Claim 9 (see '675: ¶ 68; Examples 28-31).

Instant Claim 2 is directed to a granulated product wherein at least about 35% by weight with respect to the total weight of the product does not pass through a 100-mesh sieve. The instant specification defines 100-mesh sieve as a sieve having a pore size

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of 149 microns (see page 7, line 9). The granulated product disclosed by WO '704 is sifted through a pore size of 420 micron mesh (see '675: Example 1). It would be reasonable, because the pore size used by WO '704 is 2.5 times larger than the pore size of a 100-mesh sieve, that at least about 35% by weight of the granulated product as disclosed by WO '704 would not pass through a 100-mesh sieve. Accordingly, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the disclosed granulated product. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).” MPEP 2112, I.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0243704 (hereafter WO '704; US 20040076675 ('675) is an English equivalent and will be referenced hereafter). As stated above, WO '704 discloses a pharmaceutical granulated product comprising a slightly water-soluble medicament (a pharmaceutical compound with poor wettability) and a surfactant. The disclosed granulated product provides improved granulatibility. WO '704 discloses an example wherein the weight ratio of Compound (Ia) (a pharmaceutical compound with poor wettability) and sodium lauryl sulfate (a surfactant) is 1:2. WO '704 further discloses a weight ratio of

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pharmaceutical compound to surfactant of 1:0.1 to 50:.01 (see '675: ¶ 59). WO '704 fails to disclose the narrower ranges disclosed in Instant Claims 4-6.

It would be obvious to one of ordinary skill in the art at the time the invention was made to optimize the weight ratio of pharmaceutical compound to surfactant through routine experimentation to that of the instantly disclosed narrower, with a reasonable expectation of success to provide improved granulatability, as taught by the prior art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

April 1, 2008